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Subject: proposed response to PTO guidelines re biotech claims
---------- Message Contents ----------

This is in response to the PTO request for comments on Interim Guidelines for Examination of Patent Applications under 35 USC 112, para. 1, "written description", directed primarily to written descriptions of biotechnological inventions.

The comments presented herein represent the views of the U.S. Department of Energy (DOE) Office of Assistant General Counsel for Technology Transfer and Intellectual Property, and DOE's Office of Health Effects and Life Sciences Research Division. DOE, along with the National Institutes of Health (NIH) is jointly involved in the Human Genome Project for mapping the entire human genome.

We have recently been provided with a draft copy of NIH, Office of Technology Transfer, proposed comments, whose views on this matter, particularly written description considerations to the patentabilit of partial DNA sequence (i.e.EST) claims employing comprising language, we support.

Specifically, as we understand the proposed PTO guidelines, use of terms like "gene", "mRNA", or "cDNA" in a preamble imply a specific structure which must be sufficiently described in the specification as to show that applicant was in possession of the claimed inventio However, use of "generic" preamble language such as "nucleic acid", "DNA", or "RNA" does not typically present a written description problem, according to the proposed guidelines, since these terms ar sufficiently general that one skilled in the art can readily envisi a sufficient number of members of the claimed genus to provide writ description support for the genus. We are not certain we agree with the distinction made in this context between, for example, RNA and mRNA. Nonetheless, use of "generic" preamble language such as "nucl acid" or "DNA", followed by open-ended "comprising" transitional language would appear to permit the length of a claimed nucleic aci sequence to be expanded indefinitely, with the identity of the adde nucleotides unknown, yielding claim coverage much broader in scope than the inventor would appear entitled to.

We strongly believe this issue should be revisited and clarified in the final guidelines.